(b) compacting a suitable amount of the ingredients including none, some or all of the active substance;

(c) dispensing in a mold or a cavity of a pre-formed container intended for storage of the solid dosage composition either an auxiliary solvent or an active substance-containing auxiliary solvent if the compacting step (b) does not include all of the active substance, wherein the active substance-containing auxiliary solvent is a solution or suspension of the active substance in the auxiliary solvent;

(d) placing the compacted solid ingredients in the mold or cavity; and

(e) removing the auxiliary solvent from the mold or cavity to form the solid dosage composition after the compacted solid ingredients and the auxiliary solvent with or without the active substance are placed therein. --.

REMARKS

In response to the Office Action dated June 28, 2002, Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the Office Action in view of the above amendment and the following remarks.

The specification has been amended to correct errors. Inadvertently, the specification included incorrect description of the commercially available disintegration agents Primojel®, Polyplasdone® XL, and Kollidon® CL . Primojel is a sodium starch glycolate, and Polyplasdone XL and Kollidon CL are cross-linked poly-N-vinyl-2-pyrrolidones. Unlike poly-N-vinyl-2-pyrrolidones, cross-linked poly-N-vinyl-2-pyrrolidones are not soluble in water but dispersable and swellable, making them highly suitable as disintegration agents. Website descriptions of Polyplasdone XL and Kollidon CL are enclosed with this Amendment for the Examiner's reference.

Claims 12-26 were rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of U.S. Pat. No. 6,083,531 (USP '531).

Applicant respectfully submits that claims 12-26 of the present invention are significantly different and have at least one additional limitation over claims 1-15 of USP '531. The current invention requires a disintegration agent in the dosage composition, unlike the composition of USP '531, which does not require such agent. Applicant submits that when a new invention has at least one additional limitation that was not required in the cited prior art reference, the new invention cannot be rejected under 35 U.S.C. 101 as claiming the same invention. Applicant requests reconsideration and withdrawal of the rejection.

Claims 1-11 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of USP '531.

Applicant submits that the claimed process of the present invention is highly different from the process of claims 16-19 of USP '531. Claims of 16-19 of USP '531 teach a process that deposits a solution or suspension of the ingredients into a mold to form a solid dosage form. In contrast, the present invention first forms a compacted solid form of various ingredients and the compacted from is deposited in the mold. A process that first forms a solution of ingredients and then fills a mold with the solution is highly different from the present process that first forms a compacted solid of ingredients and not a solution of all ingredients. Applicant submits that such different processes cannot be obvious variation of each other. Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claims 1-26 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. More specifically, claims 1-3 were rejected as being not clear. Applicant submits that claim 1 has been amended to clearly indicate that the compacted product is placed in the cavity or mold that holds the pre-dispensed solvent.

Claims 1-3, 15-17 and 19-21 were rejected for using the term "other". Applicant submits that the rejected claims have been amended to remove the objected term.

Claims 4 and 8 were rejected for using incomplete Markush language. Applicant submits that the claims have been amended to use proper Markush language.

Claim 8 was rejected for using the phrase "at least two different techniques", but there are at least three different techniques recited in the claim. Applicant submits that the claim clearly specifies the use of at least two techniques from the recited three techniques. Applicant respectfully submits that the rejection is not fully understood since selecting two out of the recited techniques is not improper.

Claim 10 was rejected for lacking antecedent basis. Applicant submits that claim 1, as amended, provides a clear antecedent basis.

Claims 13-26 were rejected for lacking antecedent basis for the term " pharmaceutical or veterinary solid dosage form". Applicant submits that the term has been removed from the claims.

Applicants submits that the pending claims have been amended to fully comply with the requirements of 35 U.S.C. 112, second paragraph, and request reconsideration.

Claims 12-26 were rejected under 35 U.S.C. 102 as being directed to the same invention as that of claims 1-15 of US '531. As discussed above in connection with 35 U.S.C. 101 rejection, Applicant submits that the present claims require at least one additional limitation (i.e., disintegrating agent) and, thus, cannot be anticipated by USP '531. Applicant requests reconsideration.

Claims 12-26 were rejected under 35 U.S.C. 102(b) as being anticipated by Humbert-Dorz et al. (Humbert). The Examiner stated that Humbert teaches a oral dosage form comprising active agent, filler, binding agent (disintegration agent), and talc. Applicant submits that the binding agent and the disintegration agent are not the same compound and are not interchangeable agents. Additionally, for clarification, Applicant submits that Humbert is the PCT priority document of USP '531.

Applicant submits that unlike Humbert, the present invention requires an additional and different compound in its composition. The present composition not only contains a binding agent but also contains a disintegrating agent. According to the present invention, the two agents are two different agents - i.e., one agent that holds the ingredients together as a solid dosage form (e.g., a tablet) and the other agent that helps rapid disintegration of the tablet when administered to a subject. Applicant submits that a composition requiring at least one additional ingredient

(i.e., disintegration agent) over a prior art composition cannot be anticipated by the prior art composition. Applicant requests reconsideration.

Claims 1-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert. The Examiner stated that Huber is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate, but the extra step does not impart patentability over the prior art.

Applicant respectfully submits that the conclusion made by the Examiner is improper. As illustrated at page 2 of the present specification, the present process for producing a solid dosage form has many advantage over prior art processes. For example, since the active ingredient and its excipients are not dissolved or suspended in a solvent prior to placing them in a mold, the present process assures a uniform content of ingredients, a uniform dosage weight, a less drying time, and the like. Applicant submits that mere conclusory statement that the extra step is not critical is not a sufficient basis for a rejection under 35 U.S.C. 103 when the Specification clearly indicates that the extra step provides significant advantages over prior art processes. Applicant submits that if there is any evidence to the contrary, the burden is on the Patent Office to present the evidence. Applicant requests reconsideration and withdrawal of the rejection.

Claims 12-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert. The Examiner stated that one of ordinary skill in the art would have been motivated to modify Humbert composition to obtain the claimed invention because Humbert teaches a rapidly dissolving oral dosage form.

Applicant submits that the rejection was based on a mere conclusory statement without any supporting evidence. There has to be a demonstration of motivation to modify the prior art teaching, as well as teaching of expectation of success. Applicant submits that a conclusory statement does not establish a rejection under 35 U.S.C. 103 and requests withdrawal of the rejection.

In summary, Applicant submits that the pending claims as amended are significantly different from USP '531 and Humbert, and requests reconsideration and withdrawal of the rejections.

Attached hereto is a marked-up version of the changes made to amended claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE." Additionally attached a petition for extension of time for two-months.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134.

Respectfully submitted,

Novartis Corporation

Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027
(908) 522-6794

Michael U. Lee
Attorney for Applicants
Reg. No. 35,240

Date: November 26, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

The last paragraph beginning at line 23 of page 11 has been amended as follows:

The disintegration agent can be any of those known in the art, e.g., croscarmellose Na; ~~agents based on sodium carboxymethyl cellulose and starch, e.g., Primojel®;~~ sodium glycolates of starch, e.g., Explotab® and Primojel®; cross-linked poly-N-vinyl-2-pyrrolidones, e.g., Polyplasdone® XL and Kollidon® CL; ~~starches;~~ polymethylmethacrylates, e.g., Eudispert® HV; polysaccharides, e.g., Emcosoy®; or synthetic resins, e.g., Amberlite® IRP88. Preferred disintegration agents are croscarmellose Na, ~~agents based on sodium carboxymethyl cellulose and starch~~ sodium starch glycolate (e.g., Primojel®) and cross-linked poly-N-vinyl-2-pyrrolidones (especially Polyplasdone® XL). The disintegration agent is typically present in an amount of at least 1, preferably of at least 5, and especially of at least 10 weight-% of the total dosage form, e.g. of from 1 up to 20 weight-%, especially of from 1 up to 15 weight-%.

In the claims:

Claims 1-4, 8, 13-19 and 21-25 have been amended as follows:

1. (Amended) A process for the manufacture of a solid dosage form which is rapidly dissolving in aqueous medium, wherein the solid dosage form comprising an active substance and other pharmaceutical ingredients suitable for a solid dosage and wherein the solid dosage form is a pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of

(1) either the active substance ~~-~~ or part thereof, ~~-~~ and ~~all~~ the other ingredients of the solid dosage form~~;~~, or

(2) ~~all~~ the other ingredients of the solid dosage form ~~except the active substance~~;

(b) dispensing

(1) either an auxiliary solvent or

(2) a solution or dispersion of the active substance in an auxiliary solvent~~,~~

in ~~moulds or in the~~ cavities of ~~the~~ a pre-formed container intended for storage of the solid dosage form or molds;

(c) compacting a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate prepared according to (c) ~~so obtained~~ on the top of the solvent ~~liquid~~ which according to (b)(1) or (b)(2) is in the molds ~~moulds~~ or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(e) removing the auxiliary solvent by applying a drying system to ~~the units in~~ the moulds or ~~in~~ the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried solid dosage form ~~units~~ from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid dosage form, respectively.

2. (Amended) A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of

(1) either the intended dose of the active substance ~~-~~ or part thereof ~~-~~ and ~~all~~ the other ingredients of the solid dosage form~~;~~, or

(2) ~~all~~ the other ingredients of the solid dosage form ~~except the active substance~~;

(a') transferring ~~said~~ the powder or granulate to a combined compacting/dosing system; and

(a'') placing ~~moulds or a~~ the molds or the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form within the operating range of the combined compacting/dosing system~~;~~

(b) dispensing,
(1) either an auxiliary solvent or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in the mo~~u~~lds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(c) compacting - within the combined compacting/dosing system - a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b)(1) or (b)(2) is in the mo~~u~~lds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising one or more techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure, to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form, respectively.

3. (Amended) A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of the active substance and all other ingredients of the solid dosage form;

(a') transferring ~~said~~ the powder or granulate to a combined compacting/dosing system;

(a'') placing a pre-formed container intended for storage of the solid pharmaceutical dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing an auxiliary solvent in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(c) compacting - within the combined compacting/dosing system - an amount of the powder or granulate prepared according to (a) above, which amount of powder or granulate contains the intended dose of the active substance;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b) is in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising at least two different techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure; and

(f) sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form.

4. (Twice Amended) A process according to claim 1, where in step (b) the auxiliary solvent is selected from the group consisting of water, ethanol, acetone, isopropanol and any mixtures thereof.

8. (Twice Amended) A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously or sequentially ~~interchangeably~~ at least two different

techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure.

13. (Amended) A solid ~~pharmaceutical or veterinary solid~~ dosage form ~~for oral administration~~ according to claim 12, comprising
(1) a pharmaceutically or veterinary active substance,
(2) a filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol, and
(3) a disintegration agent selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins.

14. (Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 12, comprising
(1) a pharmaceutically or veterinary active substance,
(2) mannitol, lactose, starch and microcrystalline cellulose, and
(3) a disintegration agent selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, and poly-N-vinyl-2-pyrrolidones.

15. (Amended) A solid ~~pharmaceutical or veterinary solid~~ dosage form ~~for oral administration~~ according to claim 12, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically or veterinary active substance,
(2) at least one filler,
(3) at least one disintegration agent, and
(4) optionally ~~other usual~~ pharmaceutically or veterinarily acceptable excipients,
which dosage form disintegrates when taken into the mouth within 30 seconds, and
which dosage form has a density of 400-900 mg/ml.

16. (Amended) A solid ~~pharmaceutical~~ dosage form ~~for oral administration~~ according to claim 15, consisting essentially of a homogeneous mixture of

(1) at least one pharmaceutically active substance,
(2) at least one filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol,
(3) a disintegration agent selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins, and
(4) optionally ~~other usual~~ pharmaceutically acceptable excipients.

17. (Amended) A solid ~~pharmaceutical~~ dosage form ~~for oral administration~~ according to claim 15, consisting essentially of a homogeneous mixture of
(1) a pharmaceutically or veterinary active substance,
(2) mannitol,
(3) a disintegration agent selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, and poly-N-vinyl-2-pyrrolidones; and
(4) optionally ~~other usual~~ pharmaceutically excipients.

18. (Twice Amended) A solid ~~pharmaceutical~~ dosage form ~~for oral administration~~ according to claim 12, wherein the active substance is selected from the group consisting of (a) diclofenac, ketoprofen, ibuprofen, aspirin, paracetamol, melatonin and pharmaceutically acceptable salts thereof, and (b) pharmaceutically acceptable salts of calcium, magnesium and zinc.

19. (Twice Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 15, wherein the composition contains as ~~other usual~~ one of the excipients (4) a lubricant ~~and optionally other usual excipients~~.

21. (Twice Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 15, wherein the composition contains as ~~other usual~~ the excipients (4) comprising a lubricant, and one or more sweeteners ~~and optionally other usual excipients~~.

22. (Twice Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 12, wherein the filler (2) is present in an amount of at least 30 weight-%, and the disintegrating agent (3) is present in an amount of from 0.5 up to 15 weight-% of the total dosage form.

23. (Twice Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 15, which dosage form is manufactured without applying any compression force to the mixture of the components (1), (2), (3) and optionally (4) during the last step of manufacture concerning the solid dosage form.

24. (Twice Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 12, which dosage form is manufactured without applying any freeze-drying process.

25. (Twice Amended) A solid ~~pharmaceutical or veterinary~~ dosage form ~~for oral administration~~ according to claim 15, which dosage form is manufactured by starting with the preparation of a homogeneous mixture of all the components (1), (2), (3) and optionally (4) of the dosage form.

Claim 27 has been added as follows:

27. A process for the manufacture of a solid dosage pharmaceutical composition which rapidly dissolves in an aqueous medium, comprising the steps of
(a) preparing solid powder or granule forms of ingredients for the solid dosage composition, the ingredients including an active substance;
(b) compacting a suitable amount of the ingredients including none, some or all of the active substance;
(c) dispensing in a mold or a cavity of a pre-formed container intended for storage of the solid dosage composition either an auxiliary solvent or an active substance-containing auxiliary solvent if the compacting step (b) does not include all of the active substance, wherein the active substance-containing auxiliary solvent is a solution or suspension of the active substance in the auxiliary solvent;
(d) placing the compacted solid ingredients in the mold or cavity; and

(e) removing the auxiliary solvent from the mold or cavity to form the solid dosage composition after the compacted solid ingredients and the auxiliary solvent with or without the active substance are placed therein.

Pformulate

Home

Pformulate What?

Excipients

Services

Suppliers

Resources

Advertising

Email

EXCIPIENTS

CROSPOVIDONE

1] Description: White, free flowing, compressible powder. A synthetic homopolymer o cross-linked N-vinyl-2-pyrrolidone.

Solubility: Completely insoluble in water, acids, alkalis, and all organic solvents. Hygroscopic. Swells rapidly in water. Rapidly disperses in water, but does not gel even after prolonged exposure.

Chemical Activity: Chemically inert. Has a high adsorptive capacity, forms reversible physical complexes with many molecules without the formation of covalent chemical bonds.

2] Physical Characteristics:

pH (10% slurry): 5.0 – 8.0
Moisture (Karl-Fisher): ≤ 5.0%

Product	Typical Average Particle size (microns)	Tap Density (g/cc)	Bulk Density (g/cc)
Polyplasdone XL	100	0.3	0.2
Polyplasdone XL-10	30	0.5	0.3
Polyplasdone INF-10	11	0.5	0.4

3] Applications:

Wet granulation	Disintegrant/super-disintegrant
Dry granulation	Greatest rate of swelling compared to other disintegrants
Direct compression	Greater surface area to volume ratio than other disintegrants typically used at a level of 1 to 3%
	Dissolution aid for tablets, capsules and pellets

4] Suppliers:

ISP Crospovidone JP, NF, and Crospolyvidonum Ph. Eur.
Polyplasdone
Polyplasdone XL-10
Polyplasdone INF-10

5] References:

Polyplasdone ® , Crospovidone NF, Technical Profile, ISP

Pformulate/03/08/2000

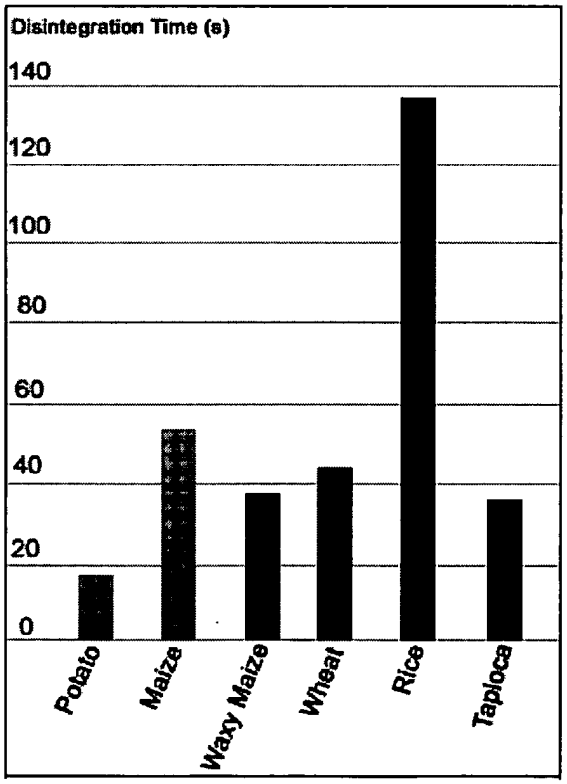
AVEBE

Primojel®

Primojel is a sodium starch glycolate USP-NF produced by cross-linking and carboxymethylation of potato starch and a subsequent purification. Both degree of cross-linking and degree of substitution were optimized in order to maintain a maximum disintegration efficiency (I).

Primojel has been allowed in the United States as a pharmaceutical ingredient under Registration Number of the Drug Master File 3015, submitted August 24,1977.

Although other starches can be used, a sodium starch glycolate prepared from potato starch is more effective than sodium starch glycolates prepared from maize, waxy maize, wheat, rice or tapioca starch.



Disintegration mechanism
Primojel takes up 23 times its weight in water. The resulting high swellin

capacity combined with high water penetration account for its high disintegration rate and efficiency (2). This makes it suitable for a variety of tablet and capsule formulations.

It was demonstrated that in the disintegration mechanism of Primojel in tablets containing soluble filler-binders such as alpha-lactose monohydrate is based on promotion of water penetration into tablets (2) resulting into dissolution of the alpha-lactose bonds.

In tablets with insoluble excepients such as dicalcium phosphate dihydrate, Primojel promotes water penetration into the tablet and develops a disintegration force needed to push the particles apart(3).

Drug dissolution rate
After the fast disintegration of tablets or capsules containing Primojel , the active ingredient will dissolve rapidly as a result of the hydrophilic nature of Primojel, and the counteracting effect of Primojel on the effects that hydrophobic lubricants have on drug dissolution rate (6) and in vivo drug absorption rate (7).

Primellose®

Primellose is a croscarmellose sodium USP-NF, a cross-linked carboxymethylcellulose sodium. Cross-linking reduces its water solubility and permits the material to swell and take up many times its weight in water without losing its fibrous integrity.

Primellose has been allowed in the U.S. as a pharmaceutical ingredient under Registration Number of the Drug Master File 9662, submitted April 21, 1992.

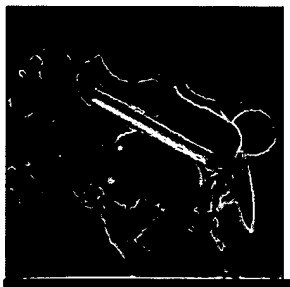
Disintegration mechanism
The excellent disintegration efficiency of croscarmellose sodium Primellos is caused by the combination of the rapid water penetration into tablets via the hydrophilic, fibrous disintegrant particles and the subsequent development of a disintegration force.

Drug dissolution
Croscarmellose sodium Primellose improves the drug dissolution rate from capsules and tablets prepared by direct compression or by wet granulation.

Application in tablets prepared by Direct Compression
In tablets prepared by direct compression, the effective concentration of Primellose is between 1 and 4%.

Application in tablets prepared by Wet Granulation
In tablets prepared by wet granulation, the effective concentration lies between 2 and 4%. The disintegrant may be incorporated intragranularly extra-granularly or equally distributed.

Top



BASF | Avebe | Ajinomoto | Aqualon | Jungbunzlauer | Danisco

Authorised Stockists of :
BASF Germany / USA,
AVEBE Holland,
AJINOMOTO Japan

Direct Imports From:
Aqualon USA,
Shin Etsu Japan,
Xyrofin-Danisco Sweetne

Fine Chemicals: Products List/Pharma

Product name	Chemical name	Packing		Specification	Rema
		Unit	Package		
Soluble Polyvinylpyrrolidone					
Kollidon 12 PF	Polyvinylpyrrolidone	50	PD	BASF	USP, PhEur
Kollidon 17 PF	Polyvinylpyrrolidone	50	PD	JPE	USP, PhEur
Kollidon 25	Polyvinylpyrrolidone	50	PD	JP	USP, PhEur
Kollidon 30	Polyvinylpyrrolidone	10, 50	PD	JP	USP, PhEur
Kollidon 90 F	Polyvinylpyrrolidone	25	CB	JP	USP, PhEur
Insoluble Polyvinylpyrrolidone					
Kollidon CL	Crospovidone	40	PD	JPE	USP, PhEur
Kollidon CL-M	Crospovidone	30	PD	JPE	USP, PhEur
Vinylpyrrolidone copolymer					
Kollidon VA 64	Copovidone	35	PD	JPE	Vinyl acetate/Vinylp copolymer PhEur, USP
Granules of Lactose monohydrate					
Ludipress	Granules of Lactose monohydrate	20	PD	BASF	Granules of La monohydrate (JP),Povidone Crospovidone Direct compre excipients
Ludipress LCE	Granules of Lactose monohydrate	20	PD	BASF	Granules of La monohydrate(Povidone(JP) Direct compre excipients
Sterilizer					
PVP-Iodine 30/06	Povidone-Iodine	10 70	FD PD	JP	USP, PhEur
PVP-Iodine 30/06 M10	Povidone-Iodine	50	PD	JP	USP, PhEur
Packaging: CB...Carton box PD...Polyethylene drum Spec.: BASF...BASF's spec. JP...Japanese Pharmacopoeia JPE...Japanese Pharmac Excipients					
Poloxamer					
Lutrol F 68	Polyoxyethylene (158) polyoxypropylene (28) glycol	102	FD	BASF	Poloxamer 18 USP, DAC, Ph

PENWEST PHARMACEUTICALS CO. NASDAQ

DESCRIPTION:

Explotab® is a cross-linked, low-substituted carboxymethyl ether of poly-α - glucopyranose obtained by the suitable treatment of potato starch and has a median particle size in the range of 35-55 μ m. About 25% of the glucose units are carboxymethylated.

APPLICATIONS AND USE:

Explotab® is remarkably effective for rapid disintegration and enhanced dissolution. Extensive manufacturing experience and laboratory studies have shown this considerable disintegration and dissolution efficiency when **Explotab®** is incorporated in tablet formulations prepared by direct compression or wet or dry granulation techniques. The mechanism by which this action takes place involves accelerated absorption of water leading to an enormous increase in the volume of granules. This results in rapid and uniform tablet disintegration.

Explotab® provides this extraordinary disintegration proficiency without demonstrating any of the major disadvantages possessed by other disintegrants. The most significant example of this is its singular attribute to maintain its swollen granules intact. Considerable experience with commercial formulation over the years indicates that there is no secondary binding.

Some of its other advantages are its white color, uniform particle size range, high bulk density, low use levels, long shelf-life stability and compatibility in the broadest spectrum of formulations.

Formulation experience indicates that **Explotab ®** provides desired results at use levels between 2-4%. It is, however, recommended that the proportion to be included in each individual formulation be determined experimentally.

BACK